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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,626	01/08/2002	Alison L. Sparks	4085-251-27	9254
7590	08/24/2005		EXAMINER	
Supervisor, Patent Prosecution Services PIPER MARBURY RUDNICK & WOLFE LLP 1200 Nineteenth Street, N.W. Washington, DC 20036-2412			CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/038,626	SPARKS, ALISON L.
Examiner	Art Unit	
Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on \_\_\_\_\_.  
2a)  This action is **FINAL**.                            2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-52 is/are pending in the application.  
4a) Of the above claim(s) 1-7 and 16-52 is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) 8-15 is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_ .

4)  Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

**1)** The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**2)** Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**3)** Claims 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 10, 12 and 14 are indefinite and confusing for the reason that they refer to "the chemiluminescent substrate delivery system of Claim 1"; however, claim 1 is directed to a non-elected invention and is therefore not a claim which is under active prosecution. To overcome this rejection, the reference to claim 1 should be deleted from claims 8, 10, 12 and 14. It is noted that without the reference to claim 1, the claims would still be complete since the "chemiluminescent substrate delivery system" is specifically "represented by the formula" which appears in the claims.

**4)** Claims 8, 10, 12 and 14 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Tomalia et al (US 5,338,532) taken in combination with the admitted prior art as set forth at page 6 of the instant specification for the reasons set forth in paragraph **7)** of the February 08, 2005 Office action.

**5)** Claims 8-15 are again rejected under 35 U.S.C. 103(a) as being unpatentable over **a)** Tomalia et al (US 5,338,532) taken in combination with the admitted prior art as set forth at page 6 of the instant specification and with **b)** Simons (Bioconjugate Chemistry (1999)) for the reasons set forth in paragraph **8)** of the February 08, 2005 Office action.

**6)** Applicant's arguments filed June 08, 2005 have been fully considered but they are not persuasive.

Applicant acknowledges that Tomalia et al do, in fact, broadly disclose optically detectable moieties associated with dendrimers including signal generators, for example, fluorescing entities (Tomalia et al: col. 7, lines 13-17; col. 8, lines 32-34; applicant's Remarks of June 08, 2005: page 23). Applicant argues, however, that the examiner has failed to establish a *prima facie* case of obviousness for the reason that the examiner has not established that there is a suggestion or motivation to substitute well known optically active moieties such as the dioxetane enzyme substrates of the admitted prior art in the conjugates of Tomalia et al, as claimed. This argument is considered unpersuasive for the reason that the motivation to combine the references is found in the applied prior art *per se*, namely in the Tomalia et al reference which establishes that it is well known in the art that dendrimers can be conjugated to a wide variety of optically detectable groups through linker moieties to obtain useful dendrimer conjugates. Criticality has not been demonstrated for the substitution of well known detectable dioxetane substrates as detectable groups in the conjugates of Tomalia et al. Tomalia et al specifically describe the desirable characteristics accruing to the use of dendrimers as a component of "carried material"-dendrimer conjugates. See Tomalia et al col. 4, lines 48-68; col. 7, lines 5-9; col. 8, line 4 – col. 9, line 38. Absent evidence to the contrary, one skilled in the art would expect that the attachment of well known dioxetane moieties to dendrimers, as claimed, would result in conjugates having the desirable features described by Tomalia et al. at col. 4, lines 48-68.

**7) THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

Art Unit: 1641

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**8)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 19, 2005

*Mary E. Ceperley*  
Mary (Molly) E. Ceperley  
Primary Examiner  
Art Unit 1641